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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,300	06/21/2007	Eric Thor Fossel	S1509.70037US01	7179
23628 7590 05/09/2011 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER TREYGER, ILYA Y	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 05/09/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,300	<b>Applicant(s)</b> FOSSEL, ERIC THOR	
	<b>Examiner</b> ILYA Y. TREYGER	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1,5,6,11,13,16-19 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4,7-10,12,14,15,20-23 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/08/2011</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claim 12 is amended.
2. Claims 1, 5, 6, 11, 13, 16-19 and 24-26 are canceled.
3. Claim 30 is new.
4. Claims 2-4, 7-10, 12, 14, 15, 20-23, and 27-30 are examined on the merits.

### ***Response to Amendment***

5. Objection of claim 19 is withdrawn in view of cancelation of the claim.
6. Rejection of claims 12 and 16 under 35 U.S.C. 112, second paragraph and 4<sup>th</sup> paragraph is withdrawn based on the amendment made to the claims.

### ***Response to Arguments***

7. Applicant's arguments filed 08/06/2010 have been fully considered but they are not persuasive:
8. With respect to claims 4, 20 and 29, Applicant argues that neither Fossel nor Falk teaches or suggests rubbing a delivery vehicle into a breast, and the Patent Office has not demonstrated that the prior art teaches each element claimed, i.e. breast.

However, since the skin covering the human breast has substantially the same anatomical and morphological structure as other parts of the skin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Fossel the step of rubbing a cream into the skin, as taught by Falk in order to improve therapeutic effect to the treatment (Falk, col. 12, line 16) and increase absorption of the cream caused by increasing the friction that in its turn increases the area of contact of cream with the skin, and thus improves absorption and penetration.

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In addition, in response to applicant's argument that Fossel does not teach or suggest rubbing a delivery vehicle comprising L- arginine into a breast, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

9. With respect to claim 2, Applicant's arguments are substantially identical to arguments discussed above.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 3, 4, 7-10, 12, 14, 15, 19-23 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169) in view of Falk et al. (US 5,824,658).

13. In Re claims 4, 29 and 30, Fossel discloses the method comprising an act of:

applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the skin covering the breast is a selected area of skin, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

With regard to limitation "for a period of time sufficient to reduce sagging", it is noted that time sufficient to reduce sagging is both indefinite and subjective, i.e. differs from patient to patient depending on number of factors, such as age, collagen content of the skin, particular clinical condition of the skin, etc., and therefore any adventives is necessarily to be applied for a period of time sufficient for providing the desired effect. Fossel does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.

Falk teaches the method of treating the skin by rubbing a gel or cream by rubbing into the skin (col. 12, lines 12-15).

Since the skin covering the human breast has substantially the same anatomical and morphological structure as other parts of the skin, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Fossel the step of rubbing a cream into the skin, as taught by Falk in order to improve therapeutic effect to the treatment (Falk, col. 12, line 16) and

increase absorption of the cream caused by increasing the friction that in its turn increases the area of contact of cream with the skin, and thus improves absorption and penetration.

14. In Re claims 3 and 19, Fossel discloses the method wherein the delivery vehicle is a cream (P. 1, [0015], ln. 1-2), wherein for examination purposes claim 19 is considering of being dependent on claim 16.

15. In Re claim 7, Fossel discloses the method wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what reads on "at least 5%" as claimed.

16. In Re claims 8 and 21, Fossel discloses the method wherein the delivery vehicle comprises the water or the oil (P. 1, [0015], ln. 7).

17. In Re claims 9 and 22, Fossel discloses the method fully capable to be repeatable (P. 1, [0015], ln. 1-3).

18. In Re claim 10, Fossel discloses the claimed invention discussed above, as applied to claim 9, but does not expressly disclose the method comprising repeating the act of reapplying the delivery vehicle to the region of skin between 2 and 30 times, inclusively, within a time period of about 30 days.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use claimed time range and overall duration of treatment, since the overall duration of the medical treatment by local action compositions and the rate of application of said compositions depend of the type of skin disease, degree of the skin lesion, and degree of the positive reaction of the patient, and therefore is the matter of routine experimentation what lies within the routine skill in the art. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)).

19. In Re claim 12, since Fossel discloses the concentration of nitric oxide donor L-arginine of 12.5% (P. 1, [0015], ln. 3) as claimed, this amount of arginine being within the claimed range is fully capable of producing the claimed function, i. e. act for at least about 3 hours, as per claim 12.

20. In Re claim 14, 15, 27, and 28, Fossel discloses the method wherein the ionic salt comprises sodium chloride, magnesium chloride, or choline chloride (P. 1, [0015], ln. 4-7), and their combined amount is 10% as per claims 15 and 28.

21. In Re claim 20, Fossel discloses the method comprising an act of: applying a base cream which is a delivery vehicle (P. 1, [0015], ln. 1-2) comprising a L-arginine which is a nitric oxide donor (P. 1, [0015], ln. 3) to the selected area of skin (P. 3, [0032], lines 5, 6) fully capable of being applied to the breast, since the breast is a selected area of skin, for a period of time sufficient for treatment fully capable for sagging skin treatment, wherein the delivery vehicle comprises a hostile biophysical environment (Abstract, lines 4-6) containing a sodium chloride (P. 1, [0010], line 3), which is a penetrating agent, and wherein the effective concentration of L-arginine is 12.5% (P. 1, [0015], ln. 3) what encompasses "at least 5%" as claimed.

With regard to limitation "for a period of time sufficient to produce a smoother surface of the breast", it is noted that time sufficient to reduce sagging is both indefinite and subjective, i.e. differs from patient to patient depending on number of factors, such as age, collagen content of the skin, particular clinical condition of the skin, etc., and therefore any adventives is necessarily to be applied for a period of time sufficient for providing the desired effect.

Fossel does not expressly disclose the method comprising rubbing the delivery vehicle into the breast.

Falk teaches the method of treating the skin by rubbing a gel or cream by rubbing into the skin (col. 12, lines 12-15).

The rationale of obviousness rejection discussed above in claim 4 is incorporated herein in its entirety.

21. In Re claim 23, Fossel discloses the claimed invention discussed above, as applied to claim 22, but does not expressly disclose the method comprising repeating the act of reapplying the delivery vehicle to the region of skin after between about 8 hours and about 48 hours after the act of applying the delivery vehicle.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use claimed time repeating range because the treatment time repeating range depends of the skin resistance level, which can vary from patient to patient, and therefore is the matter of optimization. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)).

22. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 2003/0028169) in view of Falk et al. (US 5,824,658), and further in view of Nakata et al. (US 5,332,758).

Fossel in view of Falk disclose the claimed invention discussed above, as applied to claim 4, but does not expressly disclose the method wherein the sagging is determined using viscoelasticity.



Nakata teaches that it is known to use Skin Viscoelasticity Test for skin diseases diagnostics (See Col. 17, ln. 9-43).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Fossel/ Falk with the determination of sagging skin, as taught by Nakata, because such modification would provide the most accurate diagnostic of the specific disease prior the therapeutic treatment.

### ***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/  
Examiner, Art Unit 3761

/Michele Kidwell/  
Primary Examiner, Art Unit 3761